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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IMPAX LABORATORIES, INC., Plaintiff, v. MEDICIS PHARMACEUTICAL CORP., Defendant.	Case No. C08-00253 MMC **MEDICIS' MOTION TO DISMISS** Date: April 11, 2008 Time: 9:00 a.m. Ctrm: #7, 19th Floor The Honorable Maxine M. Chesney

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on April 11, 2008 at 9:00 a.m. or as soon thereafter as counsel may be heard in the above Court, Defendant Medicis Pharmaceutical Corp. ("Medicis") will and hereby does move this Court to dismiss the declaratory judgment complaint of Plaintiff IMPAX Laboratories, Inc. ("IMPAX"). This motion is based upon the memorandum below, the accompanying declarations in support of the motion, the proposed order, the complete record of this action, evidence and argument presented at the hearing on this motion, and all matters of which the Court may take judicial notice.

RELIEF REQUESTED

Medicis respectfully seeks an Order dismissing IMPAX's declaratory judgment complaint under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. In the alternative, Medicis requests that this Court exercise its discretion to decline declaratory judgment jurisdiction.

I.
INTRODUCTION

This declaratory judgment action by IMPAX is a premature and impermissible effort to obtain an advisory opinion from this Court on the validity and infringement of a patent owned by Medicis where IMPAX does not have regulatory authorization to commercially market its product, and where Medicis has not used its patent to cause IMPAX injury. IMPAX's declaratory judgment complaint asserts that IMPAX has filed an Abbreviated New Drug Application ("ANDA") seeking approval from the Food and Drug Administration ("FDA") to commercially manufacture and sell a generic copy of Medicis' proprietary acne drug, Solodyn®, and that IMPAX is entitled to a declaration that Medicis' patent directed to Solodyn® (U.S. Patent No. 5,908,838 ("the '838 patent")) is not valid or infringed.

But IMPAX's ANDA has not been approved by the FDA, and IMPAX is thus not allowed to sell its generic drug. Moreover, unlike the typical ANDA situation, Medicis has no ability to obtain a statutory stay on FDA approval. Without such approval, any injury that IMPAX might suffer under Medicis' patent is purely hypothetical, and IMPAX lacks standing to

bring this suit. In MedImmune v. Genentech, Inc., 127 S.Ct. 764, 771 (2007), the Supreme Court held that a justiciable Article III controversy is required to establish declaratory judgment jurisdiction. A justiciable Article III controversy exists only if IMPAX has suffered "actual or imminent injury caused by the defendant [Medicis] that can be redressed by judicial relief and that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgment.' " Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1338 (Fed. Cir. 2007). Because IMPAX's complaint fails on its face to show such a justiciable controversy, it should be dismissed. And, in the alternative, public policy and the totality of circumstances centered around the hypothetical nature of this dispute counsel strongly in favor of this Court exercising its discretion to decline jurisdiction.

II.

STATEMENT OF FACTS

A. Medicis Cannot Obtain Any Stay on FDA Approval

The statutory backdrop of this case is the "Hatch-Waxman Act," formally entitled The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). This Act governs the approval of new and generic drugs and is designed to promote the dual incentives of encouraging innovator companies such as Medicis to develop new drugs, while permitting generic companies such as IMPAX to incur less costs in bringing their drugs to market. See Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002). The Act thus permits generic companies through the filing of an ANDA (an "abbreviated" new drug application) to rely on the safety and effectiveness data of the innovator product by simply showing that their product is "bioequivalent" to the innovator product, rather than going through the costly exercise of developing their own data. In exchange for such benefits, the Act provides specific protections for the patent rights of innovator companies and specific mechanisms that ensure the ability of drug patent holders to protect their rights. See 21 U.S.C. § 355(j).

These patent protections are triggered by what is known as a "paragraph IV certification." A paragraph IV certification arises from the statutory requirement that new drug developers list patents related to their new drugs in the FDA's "Orange Book," formally titled

"Approved Drug Products with Therapeutic Equivalence Evaluations." 21 U.S.C. § 355(b)(1). This Orange Book listing requires any generic company that files an ANDA to make one of four "certifications" as to each listed patent. A "paragraph IV certification" is required by the ANDA filer where the ANDA filer asserts that it should be permitted to market its generic drug before the patent expires because it believes that the listed patent is invalid and/or will not be infringed. See 21 U.S.C. § 355(j)(2)(A)(I)-(IV). Where a paragraph IV certification is made, the ANDA filer is required to provide notice of it to the patent owner along with a detailed explanation of the factual and legal bases for the applicant's opinion that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B).

Upon receiving such a paragraph IV certification, the patent owner has an exclusive 45-day period in which to determine whether and where to file a suit for patent infringement against the ANDA filer. 21 U.S.C. § 355(j)(5)(C). The result of commencing such a suit within the 45-day period is that the FDA is automatically precluded from approving the generic company's ANDA for a period of 30 months, or until the patent infringement litigation has been resolved. 21 U.S.C. § 355(j)(5)(B)(iii). The effect of this "30-month stay" is to ensure that there will be no commercial manufacturing or selling of the generic product while the patent litigation is ongoing (up to 30 months). However, if the patentee or NDA holder does not bring an infringement suit within 45 days after receiving notice of a paragraph IV certification, the Hatch-Waxman Act provides that the ANDA applicant may bring a declaratory judgment action seeking a declaration that the patent at issue is invalid or will not be infringed by the generic drug for which the ANDA was submitted. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5) (federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over declaratory judgment actions in paragraph IV ANDA cases).

None of these paragraph IV patent protections are available for Medicis' Solodyn® product, however, as Solodyn® is one of a relatively very small number of drugs to which the paragraph IV certification requirements do not apply. That is because Solodyn® contains an antibiotic ingredient that was part of a drug that was originally (and required to be) approved under 21 U.S.C. § 357, a now-repealed provision of the Federal Food, Drug, and Cosmetic Act

relating to antibiotics. Drug manufacturers such as Medicis who utilize such antibiotic ingredients are not permitted, under FDA's interpretation of the law, to list relevant patents in the Orange Book. See P.L. 105-115 (1997), Section 125(d)(2). ANDA applicants for such products (such as IMPAX) are accordingly not required to comply with the typical paragraph IV certification requirements, and the innovator is not entitled to the statutory protections that would otherwise arise from such certifications.

The result of this anomalous situation is that Medicis was not permitted to list its Solodyn® '838 patent in the Orange Book, and IMPAX was not required to file a paragraph IV certification as to the '838 patent in its ANDA. And because there was no paragraph IV certification, Medicis cannot obtain the typical 30-month stay on approval of IMPAX's ANDA. Instead, the FDA can approve IMPAX's ANDA as soon as it otherwise determines that the regulatory requirements have been satisfied. Although, significantly, that has not happened.

B. IMPAX's Premature Declaratory Judgment Complaint

Medicis first learned of IMPAX's ANDA filing in January 2008 when Medicis first reviewed a letter from IMPAX advising Medicis that it had filed an ANDA for a generic version of Solodyn®, asserting the invalidity and noninfringement of the '838 patent, and requesting a covenant from Medicis not to sue IMPAX for infringement.[1] Wu Decl. Ex. 1 (Dec. 20, 2007, Ltr. from R. Chin to J. Shacknai). Medicis responded to IMPAX that in view of the holidays it had only just received the letter and would provide a substantive response within two weeks. Wu Decl. Ex. 2 (Jan. 11, 2008, Ltr. from S. Rodner to R. Chin). Rather than wait for the promised response, however, IMPAX filed this lawsuit four days later.

IMPAX does not allege any cognizable injury in its complaint, and asserts only that: (1) IMPAX has submitted an ANDA application to manufacture and sell generic Solodyn®, Compl. at ¶ 7; (2) Medicis claims that the use of Solodyn® is covered by the '838 patent, generic competitors face risk of a suit for infringement, and Medicis intends to enforce the '838 patent, id. at ¶¶ 9-11; and (3) Medicis has not provided IMPAX with a covenant not to sue, id. at ¶ 12.

[1] The IMPAX letter is dated December 20, 2007. Because of the holidays, the letter was not reviewed at Medicis until January 2008 when Medicis sent its January 11, 2008 letter to IMPAX. Wu Decl. Ex. 2 (Jan. 11, 2008, Ltr. from S. Rodner to R. Chin).

Based on these allegations, IMPAX claims that a justiciable Article III controversy exists.

III.
ARGUMENT

A. A Justiciable Article III Controversy Does Not Exist Over IMPAX's Premature and Preemptive Complaint

The Declaratory Judgment Act provides that, "in the case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The statutory requirement of an "'actual controversy' refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." Teva, 482 F.3d at 1337. The Supreme Court held in MedImmune that Article III "require[s] that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." MedImmune, 127 S.Ct. at 771 (citations omitted).

Under MedImmune, "all the circumstances" must demonstrate the existence of a justiciable Article III controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. "A justiciable Article III controversy requires the party instituting the action to have standing and the issue presented to the court to be ripe." Teva, 482 F.3d at 1337 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). The constitutional requirement of standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." Allen v. Wright, 468 U.S. 737, 751 (1984). "Of the three standing requirements, injury-in-fact is the most determinative: whatever else the case or controversy requirement embodies, its essence is a requirement of injury in fact." Teva, 482 F.3d at 1337 (citations omitted). An injury-in-fact must be 'personal,' 'concrete and particularized,' and 'actual or imminent.'" Id. (citing Lujan, 504 U.S. at 560). These standing requirements are not met here.[2]

[2] This motion represents a facial attack that the allegations in IMPAX's complaint, even if

1. IMPAX's ANDA Does Not Confer Standing on IMPAX

While an ANDA filing is a "technical" act of infringement, it cannot by itself confer jurisdiction over IMPAX's complaint. IMPAX must still satisfy the injury-in-fact standing requirement of Article III, as Congress "cannot expand standing beyond the Article III jurisdiction of federal courts." Teva, 482 F.3d at 1338; see also Lujan, 504 U.S. at 576 ("ignoring the concrete injury requirement" is unconstitutional). There is no actual injury to IMPAX here because it has not obtained FDA approval to market its generic drug. Because IMPAX is not engaging in any commercial manufacture or sales of its product, it is not at risk of incurring damages for patent infringement. Moreover, because there is no paragraph IV certification, there can be no 30-month stay on FDA approval, and IMPAX cannot suffer any injury that might be alleged to arise from such a stay.

The absence of jurisdictional injury is shown by Teva v. Novartis, the Federal Circuit's only post-MedImmune ANDA case. There the Federal Circuit made clear that it is not the filing of an ANDA that establishes the required jurisdictional injury for purposes of sustaining a declaratory judgment, but the patentee's subsequent actions in enforcing less than all of the Orange Book listed patents while obtaining a 30-month stay on FDA approval on the entire ANDA. Teva, 482 F.3d at 1343, 1340, n.5 (Novartis' actions caused injury-in-fact to the generic company by "placing into actual dispute the soundness of Teva's ANDA and Teva's ability to secure approval of the ANDA."). In finding the required jurisdictional injury based on the uncertainty caused to the ANDA filer by the 30-month stay, the Federal Circuit specifically distinguished a situation like here where there is no 30-month stay and nothing precluding market entry:

> [The patentee's] selective [infringement] suit creates uncertainty as to [the generic's] legal rights under its ANDA. *Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent.* In contrast, under the Hatch-Waxman Act an ANDA filer in [the generic's] situation is not legally free to enter the market because federal statutes

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assumed to be true, are insufficient on their face to establish subject matter jurisdiction. See Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004) ("In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction. By contrast, in a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction.").

> prohibit it [by providing a statutory stay on ANDA approval]. See 21 U.S.C § 355(j)(5)(B)(iii).

Id. at 1345 (emphasis added). In this case there can be no 30-month stay and thus IMPAX has not suffered any injury as it remains "legally free to market its product in the face of an adversely-held patent." Id.

The absence of jurisdiction is further underscored by the Hatch-Waxman Act's limited situation in which an ANDA filer is permitted to seek a declaratory judgment. Specifically, the Hatch-Waxman Act ensures that NDA/patent holders have the first opportunity to determine whether and where to enforce patents protecting their drugs. See 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee; the "sole purpose of requiring the passage of 45 days is to provide the patent owner and brand-name drug company the first opportunity to begin patent litigation"). It is only when this exclusive 45-day period has expired and the patentee receiving a paragraph IV certification has not brought suit that the Hatch-Waxman Act provides the ANDA filer with the opportunity to file an action for a declaratory judgment "to obtain patent certainty." 35 U.S.C. § 271(e)(5). This section requires that (1) a paragraph IV certification has been filed, and (2) the patentee has failed to sue the ANDA filer for patent infringement within 45 days of receiving notice of the paragraph IV certification. Id. Neither statutory requirement is met here.

2. No Other Alleged Medicis Conduct Can Create Jurisdictional Injury Here

Beyond its filing of an ANDA, the only other allegations made by IMPAX to support its claim of jurisdiction are that Medicis has claimed that the use of Solodyn® is covered by the '838 patent, that it intends to enforce the '838 patent (Compl. at ¶¶ 9-11), and that Medicis did not provide IMPAX with a covenant not to sue under the '838 patent. Id. at ¶ 12. These circumstances cannot confer jurisdictional standing.

Medicis has not engaged in any acts of aggression that have caused injury to IMPAX. Any statements by Medicis that it intends to defend its patent cannot create the required jurisdictional injury. In Bridgelux, Inc. v. Cree, Inc., for example, this Court rejected such an argument and dismissed a declaratory judgment complaint, concluding that the patent holder's

press releases were not sufficiently "definite and concrete" to warrant a conclusion that defendants had inflicted an "actual and imminent injury" on Bridgelux. Wu Decl. Ex. 3 at *9 (Bridgelux, Inc. v. Cree, Inc., No. C 06-6495 PJH, 2007 WL 2022024 (N.D. Cal. July 9, 2007)). "The fact that Cree stated publicly in press releases or at industry meetings that it would defend its patents is unremarkable. The same could be said of many patent-holders." Id.

Neither can Medicis' marking of Solodyn® with the '838 patent nor its alleged refusal to provide IMPAX with a covenant not to sue establish the required actual and imminent injury. It simply cannot be the case that marking a product with a patent and not providing any demanding party with a covenant not to sue on that patent are sufficient to force the patentee to defend, and a court to adjudicate, hypothetical questions of patent validity and infringement. Any other result would permit any apprehensive manufacturer to force courts to issue advisory opinions, and subject patentees to unfair harassment. While a particular manufacturer may wish to mitigate its future risk, such a generalized interest in invalidating patents cannot constitute the require actual and concrete injury for establishing standing.

This is exemplified in Prasco v. Medicis, where the district court dismissed a declaratory judgment complaint in similar circumstances and held that even if "the marking of products with the patents-in-suit were analogous to a listing of patents in the Orange Book, the court in Teva was clear that this conduct alone is not sufficient to establish an Article III controversy." Wu Decl. Ex. 4 at *3. (Prasco v. Medicis, No. 1:06cv313, 2007 WL 1974951 (S.D. Ohio July 3, 2007)). The court further concluded that "Medicis' refusal [to] grant a covenant not to sue holds little weight under the circumstances." Id. at *3. The same conclusions are compelled here.

The Supreme Court's decision in MedImmune is consistent with this result. In MedImmune, the party seeking declaratory relief was able to prevent injury only by complying with a demand from the defendant. 127 S. Ct. at 777. The Supreme Court held that a plaintiff was permitted to seek a declaratory judgment that it was not infringing a patent at the same time that it was forestalling a potentially devastating infringement action by paying royalties to the patent holder. Id. Unlike the defendant in MedImmune, Medicis has not asked IMPAX to

comply with any demands. IMPAX is not making any payments to Medicis or taking any other actions at Medicis' behest. Nor has Medicis forced IMPAX to forbear from any desired activity in order to avoid liability. Rather, IMPAX is refraining from marketing a generic form of Solodyn®, not because of any actions by Medicis, but because FDA has not approved its ANDA. There is no justiciable Article III controversy in these circumstances, and the Court should accordingly dismiss IMPAX's complaint.

B. In the Alternative, This Court Should Exercise its Discretion to Decline Declaratory Judgment Jurisdiction

The Declaratory Judgment Act confers discretion on courts to decline to exercise jurisdiction by providing that judges "*may*" declare the rights and other legal relations of any interested party, not that they *must* do so. See 28 U.S.C. § 2201(a) (emphasis added). "This text has long been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." MedImmune, 127 S. Ct. at 776-77. It is the district courts which should be vested with this discretion in the first instance "because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp." Id. at 776 (citing Wilton v. Seven Falls Co., 515 U.S. 277, 289 (1995)). Therefore, even if there is an otherwise justiciable controversy, this Court has the discretion to decline declaratory judgment jurisdiction. Public Svc. Comm'n v. Wycoff Co., 344 U.S. 237 (1952); see MedImmune ("We leave the equitable, prudential, and policy arguments in favor of such a discretionary dismissal for the lower courts' consideration on remand.").

The purposes of the Declaratory Judgment Act and the principles of sound judicial administration counsel against exercising jurisdiction here. As discussed above, IMPAX does not have regulatory approval to sell its drug, and Medicis has done nothing with its '838 patent to cause any actual or imminent injury to IMPAX. In addition, rather than provide Medicis with a meaningful opportunity to respond to its letter advising of the ANDA, as Medicis requested, IMPAX filed this preemptive strike. Allowing IMPAX to proceed in these circumstances would frustrate the Hatch-Waxman Act's purpose of ensuring that the patent holder has the first opportunity to determine whether and where to enforce its patent rights, and permitting a

declaratory judgment claim by the generic company only after that exclusive period has expired. IMPAX has entirely failed to respect that framework here. While IMPAX has taken advantage of the Hatch-Waxman Act by seeking to piggyback on Medicis' safety and effectiveness data through the filing of its ANDA, it has sought to avoid the patent protections of the Act by racing to the courthouse with this preemptive and premature declaratory judgment action.

Allowing IMPAX's declaratory judgment claim to proceed would thereby frustrate Congress's carefully engineered balance of the Hatch-Waxman Act and effectively recognize declaratory judgment jurisdiction based on no more than the filing of an ANDA and the existence of a patent covering the drug. Such a result would not only be bad policy by flooding the courts with requests for advisory opinions, it would be unconstitutional by violating the Article III requirements as set forth in MedImmune. For these reasons, principles of judicial economy and fairness weigh strongly in favor of declining to exercise declaratory judgment jurisdiction here. See, e.g., Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992) (affirming district court's discretionary decision not to exercise declaratory judgment jurisdiction over patent claims where FDA had not approved product); Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1289-90 (N.D. Cal. 1991) (same), aff'd 991 F.2d 808 (Fed. Cir. Feb. 22, 1993) (affirming dismissal; "at the time Intermedics filed its complaint, Ventritex could not have attempted to sell the Cadence in the general commercial market because the FDA had yet to grant premarket approval of the device"); Fresenius USA, Inc. v. Transonic Sys., Inc., 207 F. Supp. 2d 1009, 1012 (N.D. Cal. 2001) (exercising discretion not to exercise declaratory judgment jurisdiction over patent claims); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 111-13 (D. Mass. 1998) (same).

III.
CONCLUSION

For the foregoing reasons, this Court should grant Medicis' Motion to Dismiss.

Dated: March 5, 2008

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